

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bryan, et al.

Serial No. To Be Assigned

Filed: September 25, 2006

For: OPTIMIZED EXPRESSION OF HPV 38 L1 IN YEAST

Art Unit: _____

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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By _____ Date _____

10/594064

PATENT Case No. 21571P

IAP01 Rec'd PCT/PTO 25 SEP 2006

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Alysia A. Finnegan

Attorney _____ For Applicant(s)

Reg. No. 48,878

MERCK & CO., INC.

Patent Dept., RY60-30

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Date: September 25, 2006

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

COMPLETE IF KNOWN**Application Number**

To Be Assigned

Filing Date

September 25, 2006

First Named Inventor

Bryan, et al.

Group Art Unit

Examiner Name

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Attorney Docket Number

21571P

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
		PCT	WO 98/34640		Merck & Co., Inc.	08/13/1998
		PCT	WO 99/02694		The University of Queensland	01/21/1999
		PCT	WO 00/09157		Merck & Co., Inc.	02/24/2000
		PCT	WO 01/14416 A2		Merck & Co., Inc.	03/01/2001
		PCT	WO 02/08435 A1		Glaxo Group Limited	01/31/2002
		PCT	WO 2004/084831 A2		Merck & Co., Inc.	10/07/2004
		PCT	WO 2005/032586		Merck & Co., Inc.	04/14/2005
		PCT	WO 2005/047315		Merck & Co., Inc.	05/26/2006

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				COMPLETE IF KNOWN	
				Application Number	To Be Assigned
				Filing Date	September 25, 2006
				First Named Inventor	Bryan, et al.
				Group Art Unit	
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	21571P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bosch, et al., "The casual relation between human papillomavirus and cervical cancer", J. Clin. Path., Vol. 55, pp. 244-265, 2002.
		Breitburd, et al., "Immunization with Viruslike Particles from Cottontail Rabbit Papillomavirus (CRPV) Can Protect against Experimental CRPV Infection", J. of Virol., Vol. 69, No. 6, June 1995, pp. 3959-3963.
		Chan, et al., "Phylogenetic Analysis of 48 Papillomavirus Types and 28 Subtypes and Variants: a Showcase for the Molecular Evolution of DNA Viruses", Journal of Virology, Vol. 66, No. 10, pp. 5714-5725, 1992.
		Database Accession No. Q05138
		GenBank Accession No. #NC 001592
		Guo, et al., "Signals Sufficient for 3'-End Formation of Yeast mRNA", Mol and Cell Biology, Vol. 16, No. 6, pp. 2772-2776, June 1996.
		Guo, et al., "3'-end-forming signals of yeast mRNA", TIBS 21, pp. 477-481.
		Heidmann, et al., "Flexibility and Interchangeability of Polyadenylation Signals in Saccharomyces cerevisiae", Mol. and Cell Biology, Vol. 14, No. 7, 1994, pp. 4633-4642.
		Henikoff, et al., "Transcription Terminates in Yeast Distal to a Control Sequence", Cell., Vol. 33, June 1983, pp. 607-614.
		Hofmann, et al., "Sequence Determination of Human Papillomavirus Type 6a and Assembly of Virus-Like Particles in Saccharomyces cerevisiae", Virology, Vol. 209, 1995. pp. 506-518.
		Jansen, et al., "Vaccination with yeast-expressed cottontail rabbit papillomavirus (CRPV) virus-like particles protects rabbits from CRPV-induced papillomavirus formation", Vaccine, Vol. 13, No. 16, 1995, pp. 1509-1514.
		Kotula, et al., "Evaluation of Foreign Gene Codon Optimization in Yeast: Expression of a Mouse IG Kappa Chain", Biotechnology, Vol. 9, December 1991, pp. 1386-1389..
		Liu, et al., "Polynucleotide viral vaccines: codon optimisation and ubiquitin conjugation enhanced prophylactic and therapeutic efficacy", Vaccine, Vol 20, No. 5-6, 2002, pp. 862-869.
		McMurray, et al., "Biology of human papillomaviruses", J. Exp. Path., Vol. 82, 2001, pp. 15-33
		Neeper, et al., "Expression of the major capsid protein of human papillomavirus type 1 in Saccharomyces cerevisiae", Gene, Vol. 180, No. 1-2, pp. 1-6, 1996.

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT***(use as many sheets as necessary)***COMPLETE IF KNOWN**

Application Number	To Be Assigned
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Examiner Name	
Attorney Docket Number	21571P

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NON PATENT LITERATURE DOCUMENTSExaminer
Initials*Cite
No.

Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.

Russo, et al., "Saccharomyces cerevisiae mRNA 3' End Forming Signals are also Involved in Transcription Termination", Yeast, Vol. 11, 1995, pp. 447-453.

Schiffman, et al., "Epidemiologic Evidence Showing That Human Papillomavirus Infection Causes Most Cervical Intraepithelial Neoplasia", J. of National Cancer Inst., Vol. 85, Vol 12, 1993, pp. 958-964.

Schiller, et al., "Papillomavirus-Like Particles: Basic and Applied Studies", UK: Leeds Medical Information, 1996, pp. 101-112.

Schiller, et al., "Papillomavirus-Like Particle Vaccines", J. Natl. Cancer Inst. Monographs, No. 28, 2000, pp. 50-54.

Schiller, et al., "Developing HPV virus-like particle vaccines to prevent cervical cancer: a progress report", J. of Clin. Virology., Vol 19, 2000, pp. 67-74.

Sharp, et al., "Synonymous Codon Usage in Saccharomyces cerevisiae", Yeast, Vol. 7, 1991, pp. 657-678.

Suzich, et al., "Systemic immunization with papillomavirus L1 protein completely prevents the development of viral mucosal papillomas", PNAS USA, Vol. 92, December 1995, pp. 11553-11557

Thalenfeld, et al., "oli 1 Transcripts in Wild Type and in a Cytophasmic 'Petite' Mutant of Yeast*", J. of Biol Chem., Vol. 258, No. 23, December 10, 1983, pp. 14065-14065..

Tobery, et al., "Effect of vaccine delivery system on the induction of HPV 16L1-specific humoral and cell-mediated immune responses in immunized rhesus macaques", Vaccine, Vol. 21, 2003, pp. 1539-1547.

Zaret, et al., "DNA Sequence Required for Efficient Transcription Termination in Yeast", Cell, Vol. 28, March 1982, pp. 563-573.

Zaret, et al., "Mutationally Altered 3' Ends of Yeast CYC1 mRNA Affect Transcript Stability and Translational Efficiency", J. Mol. Biol., Vol. 176, 1984, pp. 107-135.

Zhou, et al., "Papillomavirus Capsid Protein Expression Level Depends on the Match Between Codon Usage and tRNA Availability", J. of Virol., Vol. 73, No. 6, June 1999, pp. 4972-4982.

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